Nordic position statement on justification of new types of practices involving medical exposure

The Nordic Radiation Protection co-operation

The new European directive on radiation protection reinforces the requirements for justification of medical exposures. The Nordic radiation protection authorities recommend the integration of level 2 justification into established methods for assessments of new health technologies as one approach to strengthen the justification process. A Nordic cooperation has been established between the national radiation protection authorities within the Nordic Group on Medical Applications (NGMA) to support and harmonize the national implementation of this recommendation and to strengthen the dialogue with other relevant national bodies, preferably competent health technology assessment (HTA) bodies.

Justification is one of the core principles in the international framework for radiation protection provided by the International Commission on Radiological Protection (ICRP) [1, 2]. Justification of medical exposure is done by weighing the radiation detriments against clinical benefit and should be performed at three levels:

- Level 1 of the justification process considers the use of radiation in medicine in general.
- Level 2 of the justification process considers the use of a specific procedure or method involving medical exposure with the aim to ensure that the procedure increases the diagnostic or therapeutic outcome of the exposed individual before the procedure is taken into general clinical practice.
- Level 3 of the justification process considers the individual diagnostic or therapeutic outcome from a particular procedure taking into account the characteristics of the individual exposed.

Level 1 justification is taken for granted within medical exposure, since the net benefit is identified to outweigh the radiation detriment in general. However, levels 2 and 3 of the justification process are crucial within medical exposure and have been part of the European and international radiation protection regulatory framework for many years [3, 4]. The establishment of comprehensive national systems for level 2 justification is complex and systems are still under development in many countries including the Nordic countries. The importance of level 2 justification has reiterated in the new European and international Basic Safety Standards (BSS) [5, 6] and the European Commission has identified the need for increased awareness of the challenges of level 2 justification and suggests that Member State cooperate on this issue [7].

Different approaches have been under consideration for establishment of a national formal system for level 2 justification. The Nordic radiation protection authorities recommend integration of level 2 justification into assessments of new health technologies. Assessments may be based on the health technology assessment (HTA) terminology, which is described in Appendix B.

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Integration of level 2 justification into the assessment process will be an efficient approach, since the risk-benefit evaluation to be performed in the level 2 justification process is similar to the total risk-benefit evaluation already performed in for example HTAs. This approach will ensure that the radiation detriment is evaluated as part of the total risk associated with the new practice and that level 2 justification constitute one of many aspects to be covered by the assessment.

The Nordic radiation protection authorities have identified a closer relationship between level 2 justification and HTA and other similar methods as a valuable tool for continued development of justification of medical procedures and will promote the adoption of such approaches in an effort to facilitate the harmonization of the implementation of level 2 justification.

The implementation of level 2 justification in existing systems and processes can be challenging and will not always be straightforward. It is important to include experts with sufficient competence in radiation protection to ensure that the radiation risk is properly addressed in the assessments. A close cooperation between the national radiation protection authority and other competent bodies, e.g. competent, independent HTA bodies, is encouraged to succeed with this approach. It is unrealistic for any country to have enough resources to perform comprehensive assessments for all new health technologies, and it is therefore necessary for each country to establish clear criteria for when assessments should be performed and at what level. As a first approach, a comprehensive assessment (e.g. Full-HTA) should be carried out for methods involving high level of exposure, new screening methods or if the method involves significant occupational or public exposure. Minor modifications of already established practises should be justified at a local level (e.g. by Mini-HTA) if necessary. To make the best use of available resources, the evaluation of the evidence (safety and clinical effect) should preferably be carried out through European or international cooperation while the evaluation of the consequences associated with the decision to implement the method should be made nationally.

By promoting the above approach for the implementation of level 2 justification among the Nordic and European countries, already established networks, e.g. the European HTA network, can facilitate European cooperation and harmonization of the implementation of level 2 justification at a European level as already stressed by the EC [7].

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Appendices

Appendix A – New European Basic Safety Standard for Radiation Protection

The European Council has issued a new European directive laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation [1]. As mentioned earlier, this directive has reiterated the requirements for Member States to develop a regulatory framework that provides for level 2 justification in general and especially for medical exposure.

Article 19 – Justification of practises [in general]*:*
1. Member States shall ensure that new classes or types of practices resulting in exposure to ionising radiation are justified before being adopted.
2. Member States shall consider a review of existing classes or types of practices with regard to their justification whenever there is new and important evidence about their efficacy or potential consequences or new and important information about other techniques and technologies.
…
4. Practices involving medical exposure shall be justified both as a class or type of practice, taking into account medical and, where relevant, associated occupational and public exposures, and at the level of each individual medical exposure as specified in Article 55."

Article 55 – Justification [especially for medical exposures]*:*
1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.
2. Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that:
(a) new types of practices involving medical exposure are justified in advance before being generally adopted.

The directive has to be implemented in national legislation before 6th of February 2018 and all the European Member States are now working with the transposition of this directive into national legislation and regulatory framework for radiation protection. Denmark, Finland and Sweden are all EU-countries and obliged to implement the directive, while Norway and Iceland are not. However, both Norway and Iceland have decided to, in a graded approach, to harmonize their national legislation and regulatory framework with this new EU-BSS.

The European cooperation between the Heads of the European Radiological Protection Competent Authorities (HERCA) is currently working to identify a common understanding of the requirements regarding level 2 justification in the new EU-BSS and to assist Member States in their work with the transposition of the directive into national legislation [13].

Appendix B – Health technology assessments (HTA) terminology

Health technology assessment is a systematic evaluation of available knowledge on safety and clinical effect of the method combined with an evaluation of cost-effectiveness as well as ethical, social, organizational and juridical aspects. The main purpose of a HTA is to serve as a tool for decision-making in the introduction of new health technologies and practices by ensuring that they are safe, cost-effective and associated with evidence based clinical effect. It is therefore important to continue the work to establish a national formal link between HTA and the decision-making process in health care. Further, it is crucial that this decision-making process is transparent, unbiased and based on proper stakeholder involvement.

National approaches differ, but in most countries different levels of HTA exist, often referred to as Full-, Rapid- and Mini-HTA:

- A Full-HTA is a comprehensive assessment of a health technology covering all aspects.
- A Rapid-HTA is a more limited analysis performed within a shorter timeframe and focusing mostly on the safety and effectiveness of the technology.
- Mini-HTA is a very limited assessment performed by the hospitals, reflecting the local aspects of implementing new technologies.

An HTA is also the tool used for an evidence based decision to phase-out practices that is no longer clinically effective or cost-effective. It is important to distinguish between health technology regulations (HTR) and HTAs. While HTR form a regulatory process covering all medical devices and drugs, HTA is mainly reserved for the more complex problems.

Several Nordic countries have national or regional competent HTA bodies which are members of the European HTA platform, EUnetHTA [3]. This platform is responsible for European cooperation on HTA production and has developed different tools for HTAs, including a core model for the production of HTAs. It is also the platform used to conduct European Joint Actions on HTAs, founded by the EC, like EUnetHTA Joint Action 1, 2 and 3 [4, 5, 6]. In addition, the European Commission established a European HTA Network (HTAN) in 2013 [7].

References

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